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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,336	08/22/2003	Kathryn E. Uhrich	1435.021US2	8315

21186 7590 05/05/2006

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/646,336	Applicant(s) UHRICH, KATHRYN E.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 18, 21-26 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 13, 18, 21-26 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>4/24/06</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/31/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of response to pre-exam formalities filed 11/15/2004; IDS filed 1/31/05, power of attorney filed 03/24/06 and response to election requirement filed 1/30/06.

Election Requirement

Applicant has canceled claims 12, 14-17, 19, 20 and 27-34 in response to the election requirement mailed 07/28/05, applicant has also amended claims 1, 2, 4, 13, 18, 21, 23 and 24; and applicant has further added new claims 35-40. Therefore, claims 1-11, 13, 18, 21-26 and 35-40 are pending.

Applicants elected mycophenolic acid (MPA), ester linkage in the response filed 1/30/06 in response to the election requirement. Furthermore, in telephone interview on 4/24/04 with attorney Robert Harris, applicant elected C-14 hydrocarbon chain for R². Applicant identifies claims 1-4, 7, 8, 13, 18, 21-26 and 35-40 as reading on the elected species. The search is extended to include penicillin and melphalan. Therefore, claims 1-5, 7, 8, 13, 18, 21-26 and 35-40 are examined. Claims 6 and 9-11 are withdrawn from consideration as non-elected claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. The specification does not describe all polyanhydride molecules having good number of the biologically active compounds listed in claims 4 and 5 as part of the backbone of the polyanhydride.

Claims employing these biologically active agents are not fully described in the specification; cephalexin, amoxicillin, carbidopa, levodopa and amtenac are exemplified. Thus, the specification does not inform the public of the limits of the monopoly asserted. The list of biologically active agents provided in the specification in paragraphs [0034], [0035], [0036], [0037] and [0050] of the published application represents only an invitation to experiment regarding all the possible biologically active agents claimed in the instant application that can be delivered by degradation/break down/hydrolysis of the polyanhydride molecule that they are part of.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 7, 13, 18, 21-26 and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhrich (WO 99/12990).

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The WO publication discloses polyanhydride for delivery of therapeutic salicylates (page 9, lines 22-33), antiulcerative rosaprostol, vasoconstricting drug midocrine and phenylethanolamines (page 10, lines 8-15), acyclovir, melphalan, penicillin (page 11, lines 25-36). Claims 35-40 represent the intended uses of the polymer composition or the structure that the formulation will be made into, and since the composition polyanhydride composition of the prior art and that of the instant claims are the same, the formulation/product/polyanhydride of the prior art can also be processed into the forms recited in the claims 35-40. The group contemplated for the linker group are ether, ester, amide, anhydride, carbonate, urethane or sulfide groups having alkylene group containing 1-20 carbon atoms or alkoxy groups having 2-20 carbon atoms (page 3, lines 2-9). While applicant elected C-14 hydrocarbon, claims 22-24 are included in this initial examination since that prior art 1-20 carbon atoms.

5. Claims 1-11, 13, 18, 21-26 and 35-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Domb (US 5,660,851).

Domb discloses polyanhydride ocular inserts (abstract); in embodiment A, carboxylic acid containing substances are covalently attached to a polymer that contains pendant carboxylic acid groups, the attachment is through anhydride linkage and the drug is released over time by hydrolysis of the anhydride bonds (Column 4, lines 38-46); in embodiment B, the drug is dispersed within the anhydride polymer or copolymer matrix (column 4, lines 65-64); in embodiment C, carboxylic containing substance for delivery is covalently attached to pendant carboxylic acid of the polymer through methylene diester bonds which degrades in vivo over time (column 5, lines 14-16). L-dopa, carbidopa and mycophenolic acid are few of the examples of carboxylic acid drugs that can be used in embodiments A and C (column 8, lines 20-

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65; column 10, lines 2-14; column 11, lines 25-57). While claims 35-40 recite the intended application of the polymer, Domb discloses that the composition are from into implantable devices, compressed tablets for oral use and for coating of tablets for oral controlled drug delivery (column 14, lines 56-64). In the alternate, it would have been obvious to use any of the drugs suggested by Domb in the polyanhydride with the expectation of having them be released over time according to Domb.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uhrich (WO 99/12990).

The WO publication is described above. Instant claim 8 further limits claim 3 to bucillamine, mycophenolic acid, procodazole, romurtide and ubenimex. However, melphalan and these agents recited in claim 8 are all anticancer drugs. Therefore, one anticancer drug can be used in place of another anticancer drug. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the melphalan containing polyanhydride and to use other anticancer drugs in place of the melphalan with the expectation that the polyanhydride when it hydrolyzes or biodegrades would release the anticancer agents.

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8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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